

REMARKS

The Official Action of March 28, 2008, and the prior art relied upon therein have been carefully studied. The claims in the application are now claims 1, 2, 4-9, 11, 20 and 22-30, including presently non-elected and withdrawn claims 9, 11, 20 and 22, the latter of which are hereby authorized to be canceled without prejudice by Examiner's Amendment upon allowance of the elected subject matter. Applicants' claims are respectfully submitted to define novel and unobvious subject matter and should be allowed. Favorable reconsideration and allowance are respectfully urged.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Claims 1, 7, 12 and 18 have been rejected under the second paragraph of Section 112. The rejection is respectfully traversed.

First there is nothing wrong with the term "dilute", as it is readily understandable in the context of the present invention, and even more so in view of applicants'

specification. Nevertheless, claim 1 has been amended to explicitly specify the range of a dilute solution.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 2, 4-8, 10, 12-18 and 21 have been rejected under Section 102 as anticipated by Russell-Jones et al USP 6,221,397 (Russell-Jones). This rejection is respectfully traversed.

Claim 3 has not been so rejected, and the subject matter of the dependent portion of claim 3 has now been incorporated into claim 1, thereby in effect making claim 1 correspond to claim 3 rewritten in independent form. Accordingly, applicants need not further address this rejection at the present time.

For the record, however, the amendments made above are not to be taken as any acquiescence of the rejection based on Russell-Jones, applicants hereby reserving the right (should they wish to exercise it) to pursue broader claims, including original claim 1, in a continuing application, in which case applicants would rely on sections 120 and 119.

Claim 1 has been further amended to incorporate the features of claim 10, except that the recitation "an

"unsaturated bond" has been changed to read "an unsaturated C-C bond."

Claims 1-8 and 12-19 have been rejected under Section 102 as anticipated by Illum et al 2001/000765 (Illum). This rejection is respectfully traversed.

As noted above, the subject matter of claim 10 has been introduced into claim 1. As claim 10 has not been rejected as anticipated by Illum, it now follows that claim 1 and all the claims in which depend therefrom are also not anticipated by Illum, i.e. claim 1 as amended above in part corresponds to claim 10 in amended form, not subject to the rejection. Accordingly, applicants need not address this rejection at the present time.

Again, however, the amendments are made without prejudice to applicants' rights to pursue broader claims, including original claim 1, in a continuing application if applicants choose to do so.

Claims 1-6 and 12-19 have been rejected under Section 102 as anticipated by Yamamoto et al 2003/0211166 (Yamamoto). This rejection is respectfully traversed.

As pointed out above with respect to the rejection based on Illum, the rejection based on Yamamoto also does not

include a rejection of claim 10, the dependent portion of which has been incorporated into claim 1. Accordingly, applicant need not further address this rejection at the present time.

As indicated above, the amendments made above are made without prejudice to applicants' rights to pursue broader claims in a continuing application, if applicants choose to do so.

Claims 12-19 have been deleted without prejudice. Applicants respectfully note that process language in a product claim may very well serve to characterize the product itself. For example, the process for producing a pharmaceutical (or indeed any product) may imbue that product with certain physical or chemical characteristics which cannot be properly ignored when evaluating the product.

For the record, applicants would like to add the following remarks regarding Russell-Jones and its lack of relationship to the present invention. In this connection, applicants note the Examiner's statement:

Russell-Jones discloses the process wherein the particles are formed by the crosslinking reaction of a thiol group, or mercapto group, with a carboxyl group, or the unsaturated bond of the carbonyl in a carboxyl group (column 7, lines 43 to 44)

(Page 4, lines 5 to 3 from the bottom in the Office Action).

However, this statement is not correct.

Russell-Jones refers to, as an example of crosslinking reaction, "generation of thioester between a carbonyl group and thiol group" (column 7, lines 43 to 44), while Claim 10 (now part of claim 1) of the subject application recites "reaction in which crosslinkages are formed by addition reaction between a mercapto group and an unsaturated bond". Applicants believe and submit that "generation of thioester" is distinctly different from "addition reaction", and that therefore Russell-Jones does not disclose applicants' invention.

Further, as examples of an unsaturated bond-containing group, the subject specification refers to methacryl group, acryl group, vinylsulfone group, acetylenecarbonyl group (please refer to paragraph [0025] of the subject application). In this regard, applicants have revised the term "an unsaturated bond" to "an unsaturated C-C bond" in the amended claims in order to clarify the meaning of the term.

Claims 1, 7, 8, 10, 18, 19 and 21 have been rejected as obvious under Section 103 from Yamamoto in view of Schense et al 2003/0012818. This rejection is respectfully traversed.

First, the rejection of claim 1 as anticipated by Yamamoto under Section 102, and the rejection of claim 1 as obvious from Yamamoto under Section 103 are inconsistent rejections. By the express language of Section 103, it comes into play **only** in the absence of an anticipation rejection.

On the merits, it is noted that claim 3 has not been rejected as obvious from Yamamoto in view of Schense. As claim 3 has been incorporated into claim 1, applicants need not address this rejection at the present time.

Nevertheless, applicants wish to add the following remarks with respect to the non-applicability of this rejection. Thus, claim 1 reads as follows:

1. A method for preparing crosslinked polysaccharide microparticles, which comprise the following steps:
  - a) preparing a dilute solution containing a polysaccharide derivative having a crosslinkable functional group(s) in a range from 0.1 to 5% (w/v);
  - b) dispersing the solution by spraying to form microparticulate droplets; and
  - c) concentrating the solution contained in the droplets to facilitate crosslinking reaction of the polysaccharide derivative; wherein the crosslinking reaction is a reaction in which crosslinkages are formed by addition reaction between a mercapto group and an unsaturated C-C bond.

In the method of the subject invention, a crosslinking reaction occurs in droplets formed by spraying a reaction solution, and is accelerated as the reaction solution is concentrated in the spray drying procedure. Therefore, the

method is suitable for efficient preparation of microparticles with injectable size, which encapsulate drugs, in particular proteins and peptides, without jeopardizing their pharmacological activity (please refer to pages 6 to 7, paragraph [0009] of the subject specification).

On the other hand, Yamamoto only discloses crosslinking reaction after fabrication of microspheres (please refer to Example 3). Schense discloses the formation of matrix by a Michael-type addition reaction (please refer on page 6, paragraph [0081]). However, there is no teaching or suggestion to motivate a person skilled in the art to reach the subject invention by combining a crosslinkage reaction with a spray dry procedure, and no reason to do so.

Claims 12-14, 16-19 and 21 have been provisionally rejected on the basis of obviousness-type double patenting over certain of the claims of co-pending application 10/536,031. This rejection is respectfully traversed.

First, such a rejection is premature as no claims have been allowed in application 10/536,031. Also, all the claims (except claim 1) have been withdrawn as not elected in the co-pending application.

Second, applicants believe and respectfully submit that the rejection is inconsistent with the restriction requirement, i.e. the PTO is using an improper double standard. A restriction is appropriate if the claims of different groups are **patentable distinct**. Patentably distinct means *prima facie* non-obvious. Thus, the same Section 103 standard of obviousness applies in both restriction practice and in obviousness-type double patenting. If the PTO would require restriction if claims 12-14, 16-19 and 21 were in the same application as the reference claims and the co-pending application, then there should be no double patenting rejection.

Lastly, claims 12-19 and 21 have been deleted, and consequently the obviousness-type double patenting rejection should be withdrawn for this additional reason.

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicants' claims.

Applicants believe that all issues raised in the Official Action have been addressed above in a manner that

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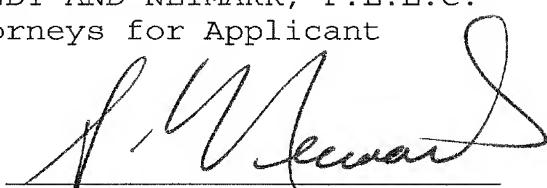
should lead to patentability of the present application.

Favorable consideration and early formal allowance are respectfully requested.

Respectfully submitted,

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